



**State of Tennessee
Department of Finance and Administration
Bureau of TennCare
310 Great Circle Road
Nashville, TN 37228**

This notice is to advise you of information regarding the *TennCare Pharmacy Program*.

Please forward or copy the information in this notice to all providers who may be affected by these processing changes.

The State of Tennessee TennCare Program continually reviews and updates the TennCare Preferred Drug List (PDL) as new classes, agents and clinical thoughts arise. The State and the TennCare Pharmacy Advisory Committee reviewed the class of Skeletal Muscle Relaxants and concluded that due to concerns over the safety and efficacy of Soma[®] (carisoprodol) and related Soma[®] combinations (carisoprodol compound, carisoprodol compound plus codeine), all carisoprodol agents (brand, generic, and combination products) would be considered non-preferred on the TennCare PDL.

Beginning **January 4, 2007**, all claims (both new prescriptions and refills) for brand and generic Soma[®] and related Soma[®] compounds will begin to deny at point-of-sale for a prior authorization. Carisoprodol is considered an addictive agent that may induce withdrawal symptoms upon discontinuation. Based on clinical judgment, a taper of products containing carisoprodol may be necessary. Prescribers are encouraged to evaluate their patients and if deemed necessary begin this process prior to **January 4, 2007**.

The following are examples of currently preferred skeletal muscle relaxants on the TennCare PDL:

- Baclofen (compares to Lioresal[®])
- Chlorzoxazone (compares to Parafon[®], Parafon[®] Forte DSC)
- Cyclobenzaprine (compares to Flexeril[®])
- Methocarbamol (compares to Robaxin[®], Robaxin[®] 750)
- Orphenadrine (compares to Norflex[®])
- Tizanidine (compares to Zanaflex[®])

Other covered agents that could be used in place of carisoprodol include generic NSAIDs and non-selective NSAIDs (which are subject to prior authorization). Examples of both are as follows:

- Diclofenac (compares to Voltaren[®])
- Ibuprofen (compares to Motrin[®])
- Naproxen (compares to Naprosyn[®])
- Meloxicam (compares to Mobic[®] - a non-selective NSAID that requires a prior authorization)

Providers are encouraged to inform patients who are on carisoprodol or carisoprodol combination products that switching to a preferred medication will decrease delays in receiving their medications.

Background on carisoprodol and the clinical decision to move to non-preferred status :

Soma[®] (carisoprodol) was approved for marketing in 1959, prior to the FDA's requirement for manufacturers to provide studies showing safety and efficacy. Concerns over the risk of carisoprodol dependence and abuse have surfaced over the last two decades. Carisoprodol is metabolized to meprobamate (a pharmacologically active drug in itself – marketed as Equanil[®] and Miltown[®] in the United States). Meprobamate was highly prescribed in the 1950s for anxiety, but then largely replaced by the newer benzodiazepines in the 60's and 70's. Meprobamate (a metabolite of carisoprodol) is not only addictive, but can be lethal in overdose. Meprobamate is classified as a controlled substance (Schedule IV) by federal law; *however*, carisoprodol does not share this federal controlled substance designation. Many states have taken steps or are in the process of classifying carisoprodol as a Schedule IV substance due concerns over the addictive nature and potential abuse of this agent. In regular users of carisoprodol, it is the meprobamate (a sedative) that accumulates in the body and causes (with carisoprodol) the sedative and subjective mood-altering effects. Carisoprodol is also known to potentiate the sedating and euphoria-inducing properties of ethanol as well as other drugs of abuse. Carisoprodol and related compounds are considered addictive agents that may induce withdrawal symptoms upon discontinuation. A tapering schedule, based on the length of time the recipient has been on carisoprodol and the recipient's current daily dose may be necessary. The tapering schedule should be subject to the provider's discretion and the recipient's tolerance levels. Currently, the State of Tennessee does not classify carisoprodol as a scheduled agent; however, the concerns of the drug have prompted the State and the TennCare Pharmacy Advisory Committee to recommend that this agent be non-preferred and subject to prior authorization.

We hope that you will find this notification useful in helping you to provide therapeutically appropriate healthcare to TennCare patients. Thank you for your participation in the TennCare program and your commitment to patient care as we continue to implement reforms and update edits.

References

- Bailey DN, Briggs JR. Carisoprodol: an unrecognized drug of abuse. *Am J Clin Pathol*. 2002 Mar;117(3):396-400.
- Jordan J, Hamer A, Ketchum KL. *Orgeon DUR Newsletter*. 2002 Oct;4(8).
- Reeves RR, Parker JD. Somatic dysfunction during carisoprodol cessation: evidence for a carisoprodol withdrawal syndrome. *J Am Osteopath Assoc*. 2003 Feb;103(2):75-80.
- Reeves RR, Beddingfield JJ, Mack JE. Carisoprodol withdrawal syndrome. *Pharmacotherapy*. 2004 Dec;24(12):1804-6.
- Toth PP, Urtis J. Commonly used muscle relaxant therapies for acute low back pain: a review of carisoprodol, cyclobenzaprine hydrochloride, and metaxalone. *Clin Ther*. 2004 Sep;26(9):1355-67.